

Depth Filtration BECO® PR Range

Depth Filter Sheets for the Pharmaceutical Industry

BECO PR depth filter sheets meet the high demands of the pharmaceutical industry. Exceptionally pure raw materials and a special production method produce BECO PR depth filter sheets with low endotoxin content. The special characteristic of this range is high endotoxin retention during the filtration of many pharmaceutical products.

The specific advantages of BECO PR depth filter sheets:

- High endotoxin retention as well as a maximum microbial retention rate.
- The innovative production process guarantees an endotoxin content of less than < 0.125 EU/ml.
- Maximum raw material purity for minimum migration of soluble ions.
- The ideal combination of various filtration mechanisms (surface, adsorption, depth filtration) and adsorptive properties ensures maximum reliability.
- Comprehensive quality assurance for all raw and auxiliary materials and intensive in-process controls ensure consistent quality of the finished products.
- Before delivery, the endotoxin content of < 0.125 EU/ml of all BECO PR depth filter sheets is tested with the help of an LAL test. A certificate is available on request.
- A Validation Guide is available upon request.

Microbial Reduction and Removal

BECO PR Steril S 100, PR Steril S 80, PR Steril 40
BECO depth filter sheets boast high microbial retention rates achieved through the tight-pored structure and an electrokinetic potential with an adsorptive effect.

These depth filter sheets are particularly suitable as pre-filters for subsequent membrane filtration because of their high capacity to retain endotoxins and colloidal components.

Fine Filtration

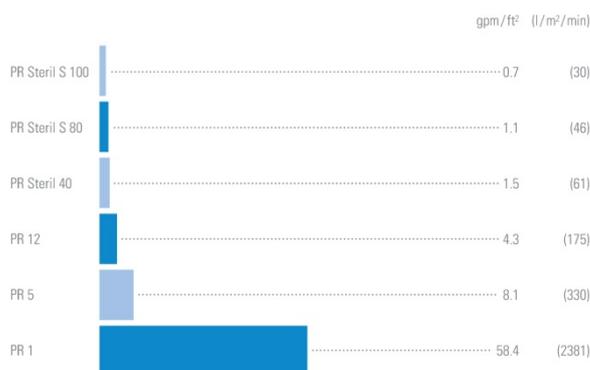
BECO PR 12

BECO depth filter sheets for achieving a high degree of clarification. These depth filter sheets reliably retain ultra-fine particles and provide bioburden reduction.

In practice, these depth filter sheets serve as ideal pre-filters for protection of membrane filters, reverse osmosis systems, and to protect chromatography columns.



Water throughput BECO PR range



Conditions: Δ p = 14.5 psi (100 kPa, 1 bar), Medium: Water at 68 °F (20 °C)

Clarifying Filtration and Coarse Filtration

BECO PR 5, PR 1

BECO depth filter sheets with large-volume cavity structure. These depth filter sheets have a high dirt-holding capacity for particles and are very suitable for clarifying filtration applications.



Physical Data

This information is intended as a guideline for the selection of BECO depth filter sheets. The water flow is a laboratory value characterizing the different BECO depth filter sheet types. It is not the recommended flow rate.

Type	Article no.	Nominal retention rate µm	Thickness in (mm)	Ash content %	Bursting strength wet		Water throughput at		Endotoxin content** EU/ml
					psi	(kPa*)	Δ p = 14.5 psi gpm/ft ²	(Δ p = 100 kPa* l/m ² /min)	
PR Steril S100	27295	0.1	0.15 (3.9)	58	> 7.3	(50)	0.7	(30)	< 0.125
PR Steril S80	27280	0.2	0.15 (3.9)	50	> 11.6	(80)	1.1	(46)	< 0.125
PR Steril 40	27240	0.4	0.15 (3.9)	49	> 7.3	(50)	1.5	(61)	< 0.125
PR 12	27212	0.8	0.15 (3.9)	50	> 18.9	(130)	4.3	(175)	< 0.125
PR 5	27205	2.0	0.15 (3.9)	50	> 8.7	(60)	8.1	(330)	< 0.125
PR 1	27200	4.0	0.17 (4.3)	48	> 6.5	(45)	58.4	(2381)	< 0.125

* 100 kPa = 1 bar

** Endotoxin content analysis after rinsing with 1.23 gal/ft² (50 l/m²) of WFI (Water for Injection)

Chemical Data

BECO depth filter sheets meet the requirements of LFGB*, Recommendation XXXVI/1 issued by BfR**, and the test criteria of FDA*** Directive CFR 21 § 177.2260.

Chemical resistance of the BECO depth filter sheets to different solvents over a contact time of 3 hours at 68 °F (20 °C). The chemical compatibilities listed in the table below are a guide only.

Solvent	Mechanical strength	Solvent appearance	Solvent	Mechanical strength	Solvent appearance	Solvent	Mechanical strength	Solvent appearance
Aqueous solutions:						Organic solvents:		
Sugar solution, 10%	r	nc	Hydrochloric acid, 1%	r	nc	Methanol	r	nc
With 1% free chlorine	r	nc	Hydrochloric acid, 3%	r	nc	Ethanol	r	nc
With 1% hydrogen peroxide	r	nc	Hydrochloric acid, 5%	r	nc	Isopropanol	r	nc
With 30% formaldehyde	r	nc	Hydrochloric acid, 10%	r	nc	Toluene	r	nc
With 10% ethanol	r	nc	Nitric acid, 1%	r	nc	Xylene	r	nc
With 40% ethanol	r	nc	Nitric acid, 3%	r	nc	Acetone	r	nc
With 98% ethanol	r	nc	Nitric acid, 5%	r	nc	Methyl ethyl ketone	r	nc
Caustic soda, 1%	r	nc	Nitric acid, 10%	r	nc	n-hexane	r	nc
Caustic soda, 2%	r	nc	Sulfuric acid, 1%	r	nc	Dioxan	r	nc
Caustic soda, 4%	r	0	Sulfuric acid, 3%	r	nc	Cyclohexane	r	nc
Ammonia solution, 1%	r	nc	Sulfuric acid, 5%	r	nc	Tetrachloroethylene	r	nc
Ammonia solution, 3%	r	nc	Sulfuric acid, 10%	r	nc	Ethylene glycol	r	nc
Ammonia solution, 5%	r	nc	Acetic acid, 1%	r	nc	Dimethyl sulfide	r	nc
			Acetic acid, 3%	r	nc	N, N-Dimethyl formamide	r	nc
			Acetic acid, 5%	r	nc			
			Acetic acid, 10%	r	0			
<i>r = resistant</i>			<i>nc = no change</i>			<i>0 = slight opalescence</i>		
<i>* = German Food, Commodity, and Feed Act</i>			<i>** = Federal Institute of Risk Assessment</i>			<i>*** = Food and Drug Administration; USA</i>		

Pyrogens/Endotoxins

Pyrogens are biological or chemical substances which can induce a rise in body temperature. One common example are endotoxins. These are cell wall components known as lipopolysaccharides, that are embedded in the outer membrane of gram-negative bacteria.

Quantitative evidence of endotoxins can be determined using the LAL test (**L**imulus **A**mebocyte **L**ysate). This method is an efficient and economical alternative to the rabbit fever test. An independent institute examines the depth filter sheets.

The endotoxin content of the specimens examined is specified in EU/ml (**E**ndotoxin **U**nits).

The measurement is carried out after rinsing with 1.23 gal/ft² (50 l/m²) of WFI water.

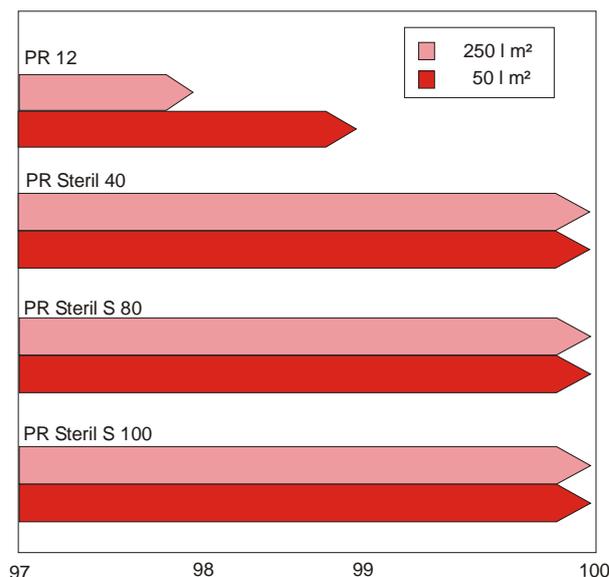
Endotoxin Retention Rate

To measure endotoxin retention, a 40% glucose solution containing a defined amount of lipopolysaccharide (LPS) in pyrogen-free water is passed through a depth filter sheet. A defined sample of the filtrate is then measured by means of the LAL test.

Filtration flow rate:	12.3 gal/ft ² /h (500 l/m ² /h)
Sampling after:	1.23 gal/ft ² and 6.14 gal/ft ² (50 l/m ² and 250 l/m ²)
Amount of endotoxin added:	2.2 mg LPS <i>E. Coli 055:B5</i> , this equals 4.4 µg LPS/ml or 4.4 x 10 ⁴ EU/ml

The endotoxin retention rate is indicated in the following graphic.

Endotoxin Retention Rate of BECO PR Depth Filter Sheets



Application Examples:

Application	Germ-reducing filtration	Fine filtration	Clarifying filtration
	PR Steril S 100, PR Steril S 80, PR Steril 40	PR 12	PR 5, PR 1
Dialysis concentrate			x
Human albumin		x	
Photoresist		x	
I-globulin		x	x
Coagulation factors		x	x
Plasma expander solutions	x	x	
Enzyme production		x	x
Hormones	x	x	x
Amino acids	x	x	x
Infusion solutions	x	x	x
Vaccine production	x	x	x
Serums from rabbits, sheep, horses, cattle, calves	x	x	x

Components

BECO depth filter sheets are made from particularly pure natural materials, i.e., finely fibrillated cellulose fibers from deciduous and coniferous trees, cationic charge carriers, and high quality, particularly pure diatomaceous earth.

Instructions for Correct Use

BECO depth filter sheets require careful handling when inserting them into the plate and frame filter. Avoid banging, bending, and rubbing the sheets. Do not use damaged depth filter sheets.

Inserting

Each BECO depth filter sheet has a rough side and a smooth side. The rough side of the depth filter sheet is the unfiltrate side; the smooth side is the filtrate side. Always ensure that the filtrate side is in contact with the clear filtrate plate when inserting the sheets.

Sanitizing and Sterilizing (Optional)

The wetted BECO depth filter sheets may be sterilized with hot water or saturated steam up to a maximum temperature of **273.2 °F (134 °C)**. The pressed filter package should be loosened slightly. Make sure to sterilize the entire filter system thoroughly. Do not apply final pressure until after the filter package has cooled down.

Sterilizing with Hot Water

The flow velocity should at least equal the filtration capacity. The water should be softened and free of impurities.

Temperature: 185 °F (85 °C)

Duration: 30 minutes after the temperature has reached 185 °F (85 °C) at all valves.

Pressure: At least 7.2 psi (50 kPa, 0.5 bar) at the filter outlet.

Sterilizing with Steam

Steam quality: The steam must be free of foreign particles and impurities.

Temperature: Max. **273.2 °F (134 °C)**
(saturated steam)

Duration: Approx. 20 minutes after steam escapes from all filter valves.

Rinsing: After sterilizing with 1.23 gal/ft² (50 l/m²) at 1.25 times the flow rate.

Filter Preparation and Filtration

Unless already completed after sterilization, Eaton recommends pre-rinsing the closed filter with 1.23 gal/ft² (50 l/m²) of water at 1.25 times the flow rate prior to the first filtration. Depending on the application, this usually equals a rinsing time of 10 to 20 minutes. Test the entire filter for leakage at maximum operating pressure.

High-proof alcohol solutions and chemical products that do not allow pre-rinsing with water should be circulated for 10 to 20 minutes. Dispose of the rinsing solution after rinsing.

Differential Pressure

Terminate the filtration process when a differential pressure of 43.5 psi (300 kPa, 3 bar) is reached. For safety reasons, a differential pressure of 21.8 psi (150 kPa, 1.5 bar) should not be exceeded in applications for separating microorganisms.

Safety

When used and handled correctly, there are no known unfavorable effects associated with this product.

Further safety information can be found in the relevant Material Safety Data Sheet, which can be downloaded from our website.

Waste Disposal

Due to their composition BECO depth filter sheets are biodegradable. Comply with relevant current regulations, depending on the filtered product.

Storage

BECO depth filter sheets consist of strongly adsorptive materials. The product must be handled carefully during shipping and storage. Store the depth filter sheets in a dry, odor-free, and well-ventilated place.

Do not expose the depth filter sheets to direct sunlight.

BECO depth filter sheets are intended for immediate use and should be used within 36 months after production date.

Available Formats

All common square or round filter sizes are available for delivery. Special formats are available on request.

Quality Assurance According to DIN EN ISO 9001

The Quality Management System of Eaton Technologies GmbH has been certified according to DIN EN ISO 9001.

This certification verifies that a fully functioning comprehensive Quality Assurance System covering product development, contract controls, choice of suppliers, receiving inspections, production, final inspection, inventory management, and shipment has been implemented.

Extensive quality assurance measures incorporate adherence to technical function criteria and chemical purity and quality recognized as safe under the German legislation governing the production of foods and beverages.

All information is given to the best of our knowledge. However, the validity of the information cannot be guaranteed for every application, working practice and operating condition. Misuse of the product will result in all warranties being voided.

Subject to change in the interest of technical progress.

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